



Medtronic

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May 30, 2000

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Food and Drug Administration
5630 Fishers Lane, Room 10-61
Rockville, MD 20852

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Re: Draft Guidance for Manufactures and FDA Reviewers on Medical Device Patent Labeling
(Docket No. 00D-0785)

Dear Sir or Madam:

Medtronic, Inc. submits the following comments in response to FDA's notice announcing the availability of, "Draft Guidance for Manufactures and FDA Reviewers on Medical Device Patient Labeling." [Federal Register Vol. 65, No. 43, March 3, 2000] Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies that restore health, extend life and alleviate pain. Medtronic, Inc.'s operations are primarily focused on providing therapeutic, diagnostic and monitoring systems for cardiac rhythm management, cardiovascular, neurological, and spinal markets that in 1999 benefited over 1.5 million patients worldwide.

Medtronic, Inc. applauds FDA's efforts in creating a guidance document to assist manufactures in the development and FDA reviewers in the evaluation of medical device patient labeling. We join in the FDA's belief that the creation of such a document serves in the best interests of the patients. In general, we feel the information presented in this guidance is well intended and in accordance with good technical communication practices. We also believe it is important that FDA, manufacturers, physicians, and patients view patient labeling as an adjunct to patient/physician communication, not a replacement. The physician is the most important and appropriate source in providing essential information to assist patients in making informed decisions relating to medical care/treatment options.

Comments to this draft guidance are being submitted by Medtronic Regulatory Affairs with significant input from Technical Communications personnel. Medtronic request that the FDA consider the following suggestions to add clarity and enhance the readability of this document:

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“Write It Right”

This guidance appears to be a revision of FDA’s August 1993 publication, “Write It Right.” To alleviate the confusion of two potentially conflicting documents, we suggest that this new guidance specify it replaces the publication “Write It Right.” In addition, the new guidance may benefit from incorporating some of the illustrations and wording from the original publication.

Descriptive Section (Length and Repetition)

In the draft guidance, the Descriptive Section could get excessively lengthy. Much of this section is intended to help the user decide whether to use the device. This is the main purpose behind the Indications, Contraindications, and Risks and Benefits sections. Since the patient’s primary goal in reading this section is deciding whether to use the device, perhaps they should be combined into a single section titled “Should I Use This Device?”

In addition, although FDA has understandable reasons for creating separate subsections for Risks/Benefits and Warnings/Precautions, it is doubtful that most patients or their families will catch or be able to discern the subtle differences in their purposes. It would be more beneficial to combine these sections, as they were under the “Write It Right” guidance.

Patients reading manuals for devices that need operating instructions may get impatient reading through separate subsections, or due to the documents size not find the operating instructions easily. Although the guidance allows manufacturers to deviate from the recommended sequence, it is industries experience that reviewers are often reluctant to allow deviations without considerable debate. If the FDA believes that separate sections are required, we suggest the guidance contain more discussion of when it is appropriate to deviate from this sequence.

Alternatives to the Device and Treatment

We believe that the explanation of alternative to the device or treatment should be included in the larger section mentioned above, “Should I Use This Device.” The content does not warrant a separate section. Explanation of alternative treatment options is part of the information needed for a patient to make a decision. This information will most likely be short, because in practice most manufacturers will need to refer users to their doctor and/or other sources (e.g., Internet sites) for additional information. It is well accepted that the patient’s doctor is the most appropriate source to explain alternatives. The fact that alternative treatments may become available after publication of patient labeling for a particular device reinforces the appropriateness of physicians being the primary source to provide the patient with the most current alternatives available.

Indications and Contraindications

We do not believe the terms indications or contraindications should be included in the patient manuals. They are regulatory/medical terms and are not necessary to explain the concepts. Even very educated lay people may not understand them, and therefore decrease readability. Alternative language to these terms could be, “When Should This Device Be Used”, or “Who Should Use This Device.”

Leaving out Sections that are Non Applicable

If there are no contraindications or setup instructions, the guidance should allow manufacturers to omit those sections. The guidance documents states we must include these sections with a note that they don't apply. Inclusion of sections that do not contain content make the document appear more cluttered and difficult to read. In addition, if some sections do not contain content, it tends to make users think that other sections may not be valuable, and they may not read them carefully.

Headlines

Some, but not all, of the headlines in the guidance are in imperative voice directed at manufacturers. This is awkward and potentially confusing. The headlines should describe the content of the section. We recommend the headlines contained in Attachment A at the end of this document. We feel that it would be clearer to put the directions to manufacturers in the text, and possibly into the checklist.

We believe that it is appropriate that the FDA does not prescribe the wording for headlines in the patient labeling. The headings should be specific to devices and information needs.

Warnings

The draft guidance is confusing regarding the placement of warnings. The suggested sequence clearly shows a separate warnings section, but the appendices recommend placing warnings close to operating instructions or wherever they're applicable.

Precautions

Appendix E misuses the term "precaution." A precaution is an action someone can take to prevent a problem. The wording alerting users of a problem is "caution."

"Writeability"

The term "writeability" in appendix B is misleading. Our aim is not to increase the ability of text to be written, but to be read. We assume the aim was to separate the previous section (which focused on measuring readability) from the principles for increasing readability. We recommend just leaving out the term, and talking about writing for increased comprehension.

Glossary/Index

The glossary and index are two separate sections, and should be shown as such in the suggested order and in the sections.

Also, the guidance is inconsistent in recommending placement of the glossary, twice recommending it go after the Table of Contents, but showing it before the index in the suggested sequence. Perhaps this is a typo. Although there is some practice putting it at the beginning, it's

potentially obtrusive there. It's more common and logical for it to appear before the index. We agree that the glossary should be included in the Table of Contents.

Tables

On page 34 the guidance recommends using tables, but recommends against it on page 36. It would be more helpful to suggest when tables are appropriate.

Thank you for the opportunity to comment on this draft guidance document.

Sincerely,

Medtronic, Inc.

A handwritten signature in black ink, appearing to read "C. Whitacre".

Chip Whitacre

Director, Corporate Regulatory and Clinical Affairs

ATTACHMENT A

Suggested Headlines in Sequence

Table of Contents

Should I Use This Device?

 Purpose and Benefits of the Device

 When the Device Should Not Be Used [including Risks and Alternatives]

Device Description

Warnings and Precautions

What to Expect [optional]

Operating Instructions (when applicable)

 Setting up [the device]

 Checking out [the device]

 Operating [the device] [This may consist of several headlines]

 Monitoring [the device]

 Cleaning

 Maintenance

 Storage

 Replacing [the device]

 Accessories

Travel

Troubleshooting

Glossary

Index

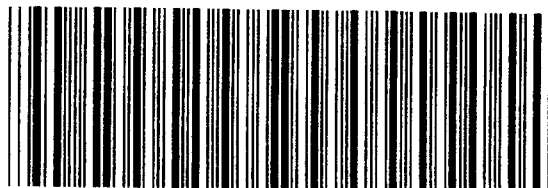
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Date 6/1/00Sender's Name Dan's Computer Phone (612) 514 6207Company MEDTRONIC INCAddress 7000 CENTRAL AVE NECity MINNEAPOLIS State MIN ZIP 55432**2 Your Internal Billing Reference Information** Ext Center 40328**3 To**
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(To "HOLD" at FedEx location, print FedEx address here) Dept./Floor/Suite/RoomCity Rockville State MD ZIP 20852**For HOLD at FedEx Location check here**☐ **Hold Weekday**
(Not available with
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(Available for FedEx Priority Overnight
and FedEx 2Day only) (Not available at all locations)**For WEEKEND Delivery check here**☐ **Saturday Delivery**
(Available for FedEx Priority
Overnight and FedEx 2Day only)☐ **NEW Sunday Delivery**
(Available for FedEx
Priority Overnight only) (Extra Charge. Not
available at all locations)

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(Next business morning)
☐ FedEx First Overnight
(Earliest next business morning delivery to select locations) (Higher rates apply)
☐ FedEx 2Day
(Second business day)
☒ FedEx Standard Overnight
(Next business afternoon)
☐ FedEx Express Saver
(Third business day)
FedEx Letter Rate not available. Minimum charge: One pound rate.**4b Express Freight Service Packages over 150 lbs.** Delivery commitment may be later in some areas.☐ FedEx Overnight Freight
(Next business day)
☐ FedEx 2Day Freight
(Second business day)
☐ FedEx Express Saver Freight
(Up to 3 business days)
(Call for delivery schedule. See back for detailed descriptions of freight services.)**5 Packaging**
☒ FedEx Letter
(Declared value limit \$500)
☐ FedEx Pak
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☐ FedEx Tube
☐ Other Pkg.**6 Special Handling**
Does this shipment contain dangerous goods? ☐ No ☐ Yes (One box must be checked)
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*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information. Credit Card Auth.

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